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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/509,239	09/24/2004	Johannes Johanna Van Herk	NL 020256	1780	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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		Application No.	Applicant(s)	
		10/509,239	VAN HERK ET AL.	
	Office Action Summary	Examiner	Art Unit	
		Rex Holmes	3762	
Period fo	 The MAILING DATE of this communication app or Reply 	ears on the cover sheet with the c	correspondence address	
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tirn vill apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).	
Status				
2a)⊠	Responsive to communication(s) filed on <u>10 Sec</u> This action is FINAL . 2b) This Since this application is in condition for allower	action is non-final.	osecution as to the merits is	
٠,١	closed in accordance with the practice under E			
5.	ion of Claims			
4)⊠ 5)□ 6)⊠ 7)□ 8)□	Claim(s) <u>1-16</u> is/are pending in the application. 4a) Of the above claim(s) <u>3 and 5</u> is/are withdra Claim(s) is/are allowed. Claim(s) <u>1,2,4 and 6-16</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/or ion Papers	awn from consideration.		
9)	The specification is objected to by the Examine	r		
·	The drawing(s) filed on is/are: a) acce		Examiner.	
	Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).	•
11)	Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Ex	= : :		
Priority (under 35 U.S.C. § 119			
a)	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau See the attached detailed Office action for a list of	s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage	
	ce of References Cited (PTO-892)	4) Interview Summary		
3) Infor	ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date	Paper No(s)/Mail Date of Informal F 6) Other:		

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DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claim 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Byers et al. (U.S. Pat. 4,969,468 hereinafter "Byers") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Byers.
- 4. Regarding claims 7 and 10, Byers discloses a electrode array for sensing physiological signals through the skin, made out of a conductive flexible/stretchable material with projections made out of metal that are arranged in a uniform pattern on the surface of the electrode (e.g. Col. 7, II. 18-25; Col. 10, II. 22-30; Col. 12, II. 25-40; Figs. 4-6). Byers further discloses that the electrode body is sandwiched between two insulating layers with the tips of the projections sticking through the layers (e.g. Fig. 4 ("8" & "10") & Col. 6, II. 38-53).

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5. In the alternative, Byers did not expressly disclose that all of the layers are elastic, but only discloses that the base is flexible and stretchable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made all of the layers of the electrode flexible and stretchable in order to provide the predictable result of preventing the layers from breaking when the base flexes and stretches.

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 8. Claims 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byers.

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- 9. Byers teaches the claimed invention except for the elastic layer being a conductive rubber and the insulating layers being plastic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the elastic layer with a conductive rubber and the insulating layer with a plastic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.
- 10. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byers as applied to claim 7 above, and further in view of Ingman (U.S. Pub. 2002/0082668).
- 11. Regarding claims 12 and 14, Byers discloses the claimed invention except for the holes to collect sweat and prevent short circuiting. Ingman teaches that it is known to use holes in the electrode as set forth in Paragraph 16 to prevent sweat from short circuiting the conducting layer of the electro-patch. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode as taught by Byers, with holes through the electrode as taught by Ingman, since such a modification would provide the predictable result of a electrode with holes to prevent sweat from short circuiting the conducting layer of the electrode. Further it would have been obvious to one having ordinary skill in the art to put the holes between the projections as the only place to put the holes in the body of the electrode would be in the spaces between the projections.

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12. Claims 1-2, 4, 6, 11, 13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Byers in view of Owen et al. (U.S. Pat. 6,148,233 hereinafter "Owen").

- Regarding claims 1-2, 4, 6, 11 and 15, Byers discloses an electrode array for 13. sensing physiological signals, such as ECG, made out of a conductive flexible/stretchable material with projections made out of metal that are arranged in a uniform pattern on the surface of the electrode as disclosed above, but Byers fails to teach a storage and analysis device that includes wearable elastic belt. Owen teaches that it is known to use a wearable system with pad style electrodes as set forth in e.g. Column 1, lines 56-63 and Column 19, lines 30-35 to provide for monitoring ECG and treating cardiac arrest. Owen further teaches that the system includes a processor, memory and ECG analysis modules (Figs. 15-16). Owen further discloses that device includes a method where an external base station is contacted in response to a predetermined condition being sensed (e.g. Col. 4, II. 39-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the array as taught by Byers, with the portable cardiac arrest monitor as taught by Owen, since such a modification would provide the predictable result of an array with a cardiac monitor for providing a means to monitor and treat cardiac arrest without having to invasively implant a monitor.
- 14. Regarding claims 13 and 16, Byers in view of Owen discloses the claimed invention except for the elastic layer being a conductive rubber and the insulating layers being plastic. It would have been obvious to one having ordinary skill in the art at the

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time the invention was made to have modified the elastic layer with a conductive rubber and the insulating layer with a plastic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

- 15. Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection.
- 16. Regarding the use of Byers, the Applicant argues that Byers does not disclose a flexible or elastomeric electrode. The Examiner respectfully disagrees. Byers discloses that, "In general, the needles in an array would be held in relatively-fixed spacing with respect to each other. It is intended to cover by "relatively-fixed" terminology, instances in which the base is flexible, curved, stretchable, etc." It is noted that if the base is flexible or stretchable the remaining layers inherently have some degree of flexibility or stretchability, otherwise the base would be fixed and would not possess the characteristics of either flexibility or stretchability. In the alternative, Byers did not expressly disclose that all of the layers are elastic, but only discloses that the base is flexible and stretchable. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made all of the layers of the electrode flexible and stretchable in order to prevent them from breaking when the base flexes and stretches.

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Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rex Holmes whose telephone number is 571-272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rex Holmes Examiner

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George Evanisko **Primary Examiner** Art Unit 3762